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PCT/JP2003/007173

## PATENT COOPERATION TREATY



## PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT2094HM	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/JP2003/007173	International filing date ( <i>day/month/year</i> ) 06 June 2003 (06.06.2003)	Priority date ( <i>day/month/year</i> ) 07 June 2002 (07.06.2002)	
International Patent Classification (IPC) or national classification and IPC A61K 9/70, 31/4468, 47/32, 47/34, A61P 25/02, 25/04			
Applicant HISAMITSU PHARMACEUTICAL CO., INC.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a.  (*sent to the applicant and to the International Bureau*) a total of \_\_\_\_\_ sheets, as follows:

sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b.  (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 07 January 2004 (07.01.2004)	Date of completion of this report 10 May 2004 (10.05.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/007173

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- international search (under Rules 12.3 and 23.1(b))
  - publication of the international application (under Rule 12.4)
  - international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- The international application as originally filed/furnished

- the description:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- the claims:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- the drawings:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. IV Lack of unity of invention**

1.  In response to the invitation to restrict or pay additional fees the applicant has:
  - restricted the claims.
  - paid additional fees.
  - paid additional fees under protest.
  - neither restricted nor paid additional fees.
2.  This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1,  
not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
  - complied with.
  - not complied with for the following reasons:

See supplemental sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

all parts.

the parts relating to claims Nos. \_\_\_\_\_.

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**International application No.  
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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

Claims 1-12 all relate to patches formed by lamination of a support comprising a polyester film and an adhesive layer containing a drug; however, such patches are commonly used, and this does not constitute a "special technical feature" in PCT Rule 13.2.

The "special technical feature" of claim 1, and claims 3-12 in part, relates to such patches in which the surface roughness of the surface of the polyester film on the side in contact with the adhesive layer is 0.05-0.8  $\mu\text{mRa}$ .

Similarly, the "special technical feature" of claim 2, and claims 3-12 in part, relates to such patches in which the surface of the polyester film in contact with the adhesive layer has been given a sand blasting treatment.

There is thus no technical relationship among these inventions involving one or more of the same or corresponding special technical features, and they are, therefore, not so linked as to form a single general inventive concept.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	2-4, 6-10, 12	YES
	Claims	1, 5, 11	NO
Inventive step (IS)	Claims	2	YES
	Claims	1, 3-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

## 2. Citations and explanations

Document 1: JP 1-83029 U (Nitto Denko Corp.), 2 June 1989

Document 2: WO 99/53906 A1 (Hisamitsu Pharmaceutical Co., Ltd.), 28 October 1999

Document 3: JP 7-138154 A (Bando Chemical Industries, Ltd.), 30 May 1995

Claims 1, 5 and 11

The inventions set forth in claims 1, 5 and 11 are not novel and do not involve an inventive step in the light of document 1, cited in the international search report.

Document 1 discloses patches formed by laminating a support layer with an adhesive layer containing a drug, wherein the surface roughness of the surface of the support layer on the side in contact with the adhesive layer, as average centre line roughness, is 1.5  $\mu\text{m}$  or less, and cites poly(ethylene terephthalate) as said support layer (which can be a film) and antipyretic analgesics, sedative analgesics and anaesthetics as drugs which can be incorporated (claims; page 2, lines 8-15; page 8, lines 14-19; page 10, lines 5-8; and page 10, last line to page 11, last line.)

**Claims 3, 4, 9 and 10**

The inventions set forth in claims 3, 4, 9 and 10 do not involve an inventive step in the light of document 1, cited in the international search report.

A person skilled in the art could easily set parameters such as the thickness and rigidity or flexibility of the adhesive layer and the support layer in the invention disclosed in document 1 within optimum ranges by means of experimentation.

**Claims 6, 7 and 12**

The inventions set forth in claims 6, 7 and 12 do not involve an inventive step in the light of documents 1 and 2, cited in the international search report.

Given that document 2 discloses the use of a styrene/isoprene/styrene block copolymer or of polyisobutylene in the adhesive layer of a patch, and also discloses an anaesthetic type analgesic such as fentanyl citrate as the drug contained in the adhesive layer, a person skilled in the art could easily investigate the application of such an adhesive layer and drug in the invention disclosed in document 1

**Claim 8**

The invention set forth in claim 8 does not involve an inventive step in the light of documents 1 and 3, cited in the international search report.

Given that document 3 discloses the incorporation of a (macromolecular) plasticizer in a patch, a person skilled in the art could easily investigate the use of a plasticizer in the invention disclosed in document 1.

**Claim 2**

The invention set forth in claim 2 is not disclosed in any of the documents cited in the international search

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report, and is novel and involves an inventive step.

Documents 1-3, which are the most relative prior art documents, do not disclose the specific feature of patches formed by laminating a support layer comprising a polyester film with an adhesive layer containing a drug, wherein the surface of the polyester film on the side in contact with the adhesive layer has been subjected to sand blasting treatment.